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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,669	07/13/2001	Charles S.H. Young	0575/62530-A/JPW/ADM	5175
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Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036			EXAMINER HILL, MYRON G	
			ART UNIT	PAPER NUMBER

1648

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/904,669

**Applicant(s)**

YOUNG ET AL.

**Examiner**

Myron G. Hill

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, and 17- 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, and 17- 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This action is in response to the paper filed January 9, 2004.

Claims 1 and 17- 20 are under consideration in this office action.

#### ***Claim Objections Withdrawn***

Claims 2- 4 were objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant has canceled the claims and added independent claims that correspond to the canceled claims.

#### ***Rejections Withdrawn***

#### ***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 2- 4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention withdrawn.

The claims have been canceled.

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Claim 5 was rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for the said claims. The specification does not provide a repeatable method for obtaining the claimed modified adenovirus, and it does not appear to be readily available material. Applicant's deposit statement in the specification does not indicate the extent of availability of the deposit.

Applicant has supplied a statement the fulfills the USPTO requirements for deposits.

***Claim Rejections - 35 USC § 103***

Claim 1 was rejected under 35 U.S.C. 103(a) as being unpatentable over Gorziglia *et al.* (1999) and Leppard (J. of General Virology 1997, Vol 72, pages 2131-2138).

Applicant's arguments concerning what the virus of Gorziglia *et al.* expresses and that the combination do not teach the element recited in part iii) of claim 1 are persuasive.

***Rejections Maintained***

***Claim Rejections - 35 USC § 112***

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one

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skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues that the claim has been amended to make it independent and the deposit no longer requires the recited features of claim 1.

Applicant's arguments have been fully considered and not found persuasive.

The specification discloses "[a]n adenovirus vector was constructed which expresses early region 4 ORF6 protein, in the absence of expression of any other adenovirus gene (page 37, lines 19- 21). The virus can be grown on 293 cells (page 37, lines 22- 34). The specification does not teach how to make a virus that only expresses E4 orf 6 and can grow on 293. 293 cells that provide only support for E1 deleted viruses.

Thus, the lack of guidance in the specification and the prior art and the conflicting qualities the virus must possess, greatly reduces the probability that one of skill in the art would successfully obtain the claimed invention without undue experimentation.

### ***New Rejections***

Claims 1 and 17- 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are evaluated for enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The claims require an adenovirus that expresses E4 orf6 and no other early or late gene products are expressed.

The specification does not teach how to make a virus in which no other early or late gene products are expressed when E4- orf6 is expressed. The claims require that no other early or late gene products be expressed. The claims do not require that the genes not be present in the genome. Bridge and Ketner (J Virol 1989, from IDS, Exhibit 2) clearly state that if E4 orf 6 is expressed, then that allows for late gene expression to occur (abstract). The specification provides no guidance or examples on how an adenovirus can be made that has the recited functions.

The disclosure is clearly not commensurate in scope with these claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with

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these claims. Clearly there is lack of guidance directing a skilled artisan to make the virus of the claimed invention. Without specific guidance or direction and /or working examples, one of ordinary skill in the art would not be able to reproducibly practice the invention as claimed, without undue experimentation.

Claims 1, and 17- 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The burden of the written description requirement in this application for an adenovirus that expresses E4 orf6 and no other early or late gene products are expressed has not been met.

The written description in this case only sets forth an adenovirus that does not express any gene products from E4 except orf6.

Vas-Cath Inc. v. Mahurkar ((CAFC, 1991) 19 USPQ2d 1111), clearly states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See Vas-Cath at page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). It

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is respectfully submitted that the instant specification, in fact, clearly states at page 37, lines 24- 28 discloses that the VORF6 lacks the E4 region and expresses the E4 orf6 through a heterologous promoter and that E4 orf6 is sufficient to restore full virus replication. It further states that the virus is grown on is grown in 293 cells. 293 cells are known to complement adenovirus defective in the E1 region. There is no disclosure on how the rest of the virus is modified/ deleted to have the recited properties. Accordingly, there is evidence that the claimed invention was not in Applicant's possession as of the filing date sought.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see Vas-Cath at page 1115).

With the exception of an adenovirus that is deleted for the E4 region and expresses the E4 orf6 through a heterologous promoter, the skilled artisan cannot envision the claimed virus and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention and a reference to antibodies which penetrate cells (page 9, lines 14-35 of the instant specification. See *Fiers v. Revel*, ((CAFC, 1993) 25 USPQ 2d 1601) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*,((CAFC, 1991) 18 USPQ2d 1016).

Therefore only an adenovirus that is deleted for the E4 region and expresses the E4 orf6 through a heterologous promoter, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.



**Conclusion**

No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Myron G. Hill  
Patent Examiner  
May 2, 2004



JAMES HOUSEL 5/3/04  
SUPERVISORY PATENT EXAMINER  
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